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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/101,672	10/23/98	BARTLETT	02481.1503

HM12/0611
FINNEGAN HENDERSON FARABOW
GARRETT & DUNNER
FRANKLIN SQUARE BLDG SUITE 700
1300 I STREET N W
WASHINGTON DC 20005-3315

EXAMINER
WHITE, E

ART UNIT	PAPER NUMBER
1623	19

DATE MAILED: 06/11/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/101,672

Applicant(s)
BARTLETT et al.

Examiner
Everett White

Art Unit
1623



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 2, 2001
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-17, 20-26, and 29 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-17, 20-26, and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

1. The request filed on April 2, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/101,672 is acceptable and a CPA has been established. An action on the CPA follows.
2. The preliminary Amendment/Arguments filed April 2, 2001 has been received and entered into the record.
3. Claims 12-17, 20-26 and 29 are pending in the case.
4. All 35 U.S.C. statutes not cited in this Office action can be found cited in full in a previous Office action.

35 U.S.C. 103 Rejection

5. Claims 12-17, 20-26 and 29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Bartlett et al (US Patent No. 4,965,276) for the reasons already of record on page 2 of the Office Action mailed December 6, 1999.
6. Applicant's arguments filed April 2, 2001 have been fully considered but they are not persuasive. In order to accept the argument presented by Applicants in their response filed April 2, 2001, the Examiner would have to ignore the information and claims disclosed in the Bartlett et al patent. Even-though the Bartlett et al patent does not disclose examples of the effectiveness of compounds 1 and 2 as part of a single pharmaceutical composition, it is clear to the Examiner that the disclosure and claims of the Bartlett et al patent embraces a pharmaceutical composition that comprises both compounds 1 and 2 as components of a single composition. The advantages pointed out by the Applicants in their argument is base on the advantages of the combination of compounds 1 and 2 in a composition over compositions that only comprises compound 1 without the present of compound 2. Since the Bartlett et al patent discloses a composition that comprises both compounds 1 and 2 in a single composition, the advantages pointed out by Applicants does not appear to over come the rejection under 35 U.S.C. 103. The instant claims discloses that the concentration of compound 2 in the composition may be as high as 50% of compound 1 which appears to be a high enough concentration to question the patentability of the instant claims over

a composition disclosed in the Bartlett et al patent that comprises both compounds 1 and 2. Note that obviousness under section 103 does not required absolute predictability of success -- all that is required is a reasonable expectation of success. Accordingly, the rejection of Claims 12-17, 20-26 and 29 under 35 U.S.C. 103(a) as being unpatentable over the Bartlett et al patent is maintained.

7. **Summary:** All the pending claims (12-17, 20-26, and 29) are rejected.

ACTION MADE FINAL

8. All claims are drawn to the same invention claimed in the parent application prior to the filing of this Continued Prosecution Application under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing under 37 CFR 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Examiner's Telephone Number, Fax Number, and Other Information

9. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E. White

White

June 6, 2001



GARY GEIST
SUPERVISORY PATENT EXAMINER
TECH CENTER 1600